DEC 3 0 2003

510(k) Summary of Safety and Effectiveness

BEBIG brachytherapy I-125 source

p1/2

K033781

December 01, 2003

Company Name

BEBIG Isotopen- and Medizintechnik GmbH
Robert Rössle Str. 10
13125 Berlin, Germany
phone: ++49 30 94 10 84-0

Official Contact

Sven Langer
Regulatory Affairs

Device Name

Proprietary Name:	BEBIG IsoSeed I-125
Common Name:	Brachytherapy iodine-125 source
Classification Name:	21 CFR 892.5730 Radionuclide Brachytherapy Source, KXK

Predicate Devices used for Substantial Equivalence

Device	Premarket #
BEBIG Brachytherapy Iodine-125 Source	K 021343

Intended Use

The BEBIG I-125 sources are intended for use in the treatment of cancer with radioactive sources in close proximity to or within the tumor.

Indications for use

The BEBIG brachytherapy I-125 sources are indicated for the treatment of selected localized tumors. These sources are commonly used to treat superficial, intra-abdominal and intrathoracic tumors. Tumors of the head, neck, lung, pancreas and prostate are commonly treated. They may be used alone, or in combination with external beam radiation.

Description

The BEBIG I-125 sources are cylindrical sealed sources containing iodine-125 radioactivity. The sources are 4.5 mm long and 0.8 mm in diameter. The outer capsule of the source is composed of titanium, and is sealed at each end by laser weld. The iodine-125 is deposited within a porous ceramic tube as silver iodide (AgI). A radiopaque marker is located in the center of the ceramic tube to serve as an x-ray marker. The radiopaque marker is composed of gold alloy.

I-125 has a half live of 59.46 days and decays by electron capture with emission of characteristic photons and electrons. The titanium wall of the I-125 source absorbs the electrons.

The BEBIG I-125 sources are available in a range of activity levels. The most commonly used source activity levels for permanent implants are 0.2-0.6 mCi, other source strengths, in particular for temporary applications, are available according to customer specific order. The sources are provided non-sterile and must be sterilized before use.

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The manufacturer will adhere to the following regulations and standards:

FDA Quality System Regulation 21 CFR Part 820 Good Manufacturing Practices

ISO 9001 Quality Management Systems

ISO 13485: Medical devices quality system

ASTM Standard for Titanium: F67-00

ISO 2919 sealed radioactive sources - General requirements and classifications

ISO 9978: 1992(E) Radiation Protection-Sealed radioactive sources- Leakage test Methods

Comparison to predicate device

The BEBIG brachytherapy I-125 source is identical with the BEBIG brachytherapy I-125 source as cleared by K 021343.

Summary

In Summary, the BEBIG brachytherapy I-125 source is substantially equivalent to a legally marketed device. Quality System Controls assure the device is substantially equivalent to the predicate device with respect to its performance, safety, and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 3 0 2003

Mr. Sven Langer
Regulatory Affairs
BEBIG Isotopen- und
Medizintechnic Gmbh
Robert-Rossle-StraBe 10
D-13125 Berlin
GERMANY

Re: K033781
Trade/Device Name: BEBIG IsoSeed I-125
Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: Class II
Product Code: 90-KXK
Dated: December 1, 2003
Received: December 4, 2003

Dear Mr. Langer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indication for Use

K033781

510(k) Number (if known):

Device Name: BEBIG brachytherapy iodine-125 source (IsoSeed I-125)

Indications for Use:

The BEBIG brachtherapy I-125 sources are indicated for the treatment of selected localized tumors. These sources are commonly used to treat superficial, intra-abdominal and intrathoracic tumors. Tumors of the head, neck, lung, pancreas and prostate are commonly treated. They may be used alone, or in combination with external beam radiation.

Prescription Use___X___ (Part 21 CFR 801 Subpart D) AND / OR Over-The –Counter Use_____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K033781